REMARKS

Applicants acknowledge with appreciation the time and courtesies extended by the examiner toward applicants' representative during a telephone interview on May 12, 2006 and May 20, 2006. The examiner's insights and comments have advanced the prosecution of the case. In particular, the outstanding rejections were discussed. Further discussion involved potential claim amendments in view of the non-statutory subject matter rejections. Applicants address the examiner's remarks in the order presented in the April 20, 2006 Office Action. All claim amendments are made without prejudice and do not represent acquiescence in any ground of rejection.

STATUS OF THE CLAIMS

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 are currently pending. Claim 4 was canceled. Claims 1 and 28 were amended, incorporating the language of canceled claim 4 into each claim. No new matter has been added by this amendment. With this Reply, claims 1-3, 8, 13, 16-25, 28-32 and 39-41 will be pending.

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 stand rejected under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter.

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 remain rejected under 35 U.S.C. § 102(a) as being anticipated by Hertogs *et al.* (Antimicro. Agents and Chemo. (March 2000) Vol. 44, pages 568-573).

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Applicants' representative has submitted a Supplemental Information Disclosure Statement (SIDS) with this Reply for the following reasons. Applicant's representative has been made aware of a related and co-pending application, Application No. 10/258,150, entitled "Methods for Measuring Drug Resistance" ("the 150 application"; filing date October 18, 2002; Group Art Unit 1648; Examiner Louise Wang Zhiying) which is the national stage filing of a PCT application which was filed through the EPO.

The pending application which is the subject of the April 20, 2006 Office action, is a direct U.S. nonprovisional filing and claims priority to two U.S. provisional applications, 60/197606 (filed 19 April 2000) and 60/213219 (22 June 2000). The pending application has a 18 April 2001 filing date. The 150 application also claims priority to the same two provisional applications listed above. The 150 application has a 18 October 2002 filing date.

The Supplemental Information Disclosure Statement incorporates all references cited in the 150 application and related international applications in various jurisdictions.

In addition, Applicants' representative is submitting the first Office Action that issued regarding the 150 application on May 25, 2006 as Exhibit A.

REJECTIONS UNDER 35 U.S.C. § 101

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 was rejected under 35 U.S.C. § 101 because the claimed invention is allegedly directed to non-statutory subject matter. The examiner stated that the claims must be amended to clearly describe a physical step as it was not apparent where this step occurs in the method.

More specifically, the examiner is of the opinion that the method and computer program of the instant claims is directed determining a phenotype comprising obtaining genetic sequence data, identifying a mutation pattern, searching a database; obtaining a database phenotype, and determining a phenotype of the sequence based upon the database phenotype. The claims do not produce a result which is concrete, tangible, and useful. According to the examiner, the claims merely encompass manipulations of abstract ideas (data) without producing a specific output that meets the concrete, tangible, and useful criteria. No specific outcome is set forth in the claims such that the steps of the method produce a result that is immediately concrete, tangible, and useful.

The examiner stated that descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material". In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component (The definition of "data structure" is "a physical or logical relationship among elements. Designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993)). "Nonfunctional descriptive material" includes, but is not limited to, music, literary works and a compilation or mere arrangement of data.

According to the examiner, both types of "descriptive material" are nonstatutory when claimed as descriptive material per se. Warmerdam, 33 F.3d at 1360, 31 USPQ2d at 1759. When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material, *i.e.*, abstract ideas, stored in a computer-readable medium, in a computer, or on an electromagnetic carrier signal does not make it statutory. See Diehr, 450 U.S. at 185-86, 209.

The rejection of claims 1-4, 8, 13, 16-25, 28-32 and 39-41 under 35 U.S.C. § 101 as it pertains to claims 1-4, 8, 13, 16-25, 28-32 is obviated by amendment. The rejection of claims 39-41 is traversed.

Applicants amended the claim 1 and 28 for clarity. Claim 4 was canceled and claims 1 and 28 were amended, incorporating the language from canceled claim 4 into each claim.

Regarding claim 39, applicants traverse. Claim 39 is directed to a computer program for determining a phenotype of a retrovirus, wherein the retrovirus is the Human Immunodeficiency Virus, wherein the program is comprised on a computer readable medium.

According to the November 2005 Interim Guidelines (Interim Guidelines), computer programs claimed as "computer listings per se, *i.e.*, the descriptions or expressions of the programs, are not physical "things." They are neither computer components nor statutory processes, as they are not "acts" being performed. Such claimed computer programs do not define any structural and functional interrelationships between the computer program and other claimed elements of a computer which permit the computer program's functionality to be realized." See Interim Guidelines, Annex IV, page 53, first paragraph.

However, and in contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See *In re Lowry*, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994).

As discussed in the Interim Guidelines, computer programs are often recited as part of a claim and Office personnel should determine whether the computer program is being claimed as part of an otherwise statutory manufacture or machine. In such a case, the claim remains statutory irrespective of the fact that a computer program is included in the claim. See Interim Guidelines at page 54, second paragraph.

The same result (a finding that the claims are statutory) occurs when a computer program is used in a computerized process where the computer executes the instructions set forth in the computer program. See Interim Guidelines at page 54, second paragraph. Since claim 39 is directed to a computer program for determining a phenotype of a retrovirus, wherein the retrovirus is the Human Immunodeficiency Virus, wherein the program is comprised on a computer readable medium, Applicants believe that pending claim 39 is therefore statutory under the Interim Guidelines as discussed above.

Without acceding to the propriety of the rejection of pending claims 1-4, 8, 13, 16-25, 28-32 and 39-41 under 35 U.S.C. §101, applicants respectfully request reconsideration of the claims as amended and as discussed above. For these reasons, applicants request the examiner to withdraw the rejection of pending claims 1-4, 8, 13, 16-25, 28-32 and 39-41 under 35 U.S.C. §101.

REJECTIONS UNDER 35 U.S.C. § 102

Claims 1-4, 8, 13, 16-25, 28-32 and 39-41 were rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Hertogs *et al.* (Antimicro. Agents and Chemo. (March 2000) Vol. 44, pages 568-573).

Claims 1-4, 8, 13, 16-25, 28-32, and 39-41 remain rejected under 35 U.S.C. § 102(a) as being anticipated by Hertogs *et al.* for the reasons set forth in the previous Action.

The examiner stated that the Declaration under 37 CFR § 1.131 was insufficient to overcome the prior art rejection under 35 USC § 102(a) over Hertogs *et al.* (Antimicro. Agents and Chemo. (March 2000) Vol. 44, pages 568-573), as the declaration was not signed by all named inventors.

The Hertogs reference should not be considered prior art under 35 U.S.C. § 102(a) because applicants' date of invention was prior to the March 2000 Hertogs publication date. In the attached Declaration under 37 C.F.R. § 1.131 ("§ 1.131 Declaration"), all named inventors declare that they completed the invention in this country, or in a NAFTA country, or a WTO member country. Their actual reduction to practice of the claimed invention, directly or through persons under their direction and control, was before the March 2000 Hertogs publication date.

The inventors also submit Exhibit A and B, attached. Exhibit A is a listing of claims, as currently pending. Exhibit B is entitled "Test Script for Validation of VIRIS" signed by Kurt Hertogs, one of the named inventors, which shows the functionality of "VircoGen II," now called "VirtualPhenotype". The date of Exhibit B is prior to March 2000.

For example, the inventors declare Exhibit B shows at page 4, ¶1.1, the "System and System Features to be tested" which discloses all the steps as claimed in pending claim 1. In particular, Exhibit B discloses "VircoGen II, *i.e.*, the prediction of genotypic resistance based on available phenotypic data."

The inventors further declare that Exhibit B shows at page 24 under the header "7. Test Summary Log" the following: "Verify the scoring of genotypic calls in the VircoGen™ database (virtual phenotypes)".

The inventors further declare that the Hertogs report discloses in Exhibit B "VircoGen II, *i.e.*, the prediction of genotypic resistance based on available phenotypic data." (see Exhibit B at page 4, ¶1.1).

The inventors further declare that the Hertogs report in Exhibit B at page 4, ¶1.1, describes, in detail, new steps to validate the calls based on phenotypic data. The new steps include: create Hot Spots from rules, or use a set of predefined Hot Spots (preferred) (see Exhibit B at page 4, ¶1.1); import a reference set of genotypic and phenotypic data (AV_Data). The program will identify sequences belonging to each Hot Spot and link them to the Hot Spots (see Exhibit B at page 4, ¶1.1); from the Hot Spots "Special" button, recalculate the Phenotypic Sets. This will link the set of corresponding phenotypes to each Hot Spot (see Exhibit B at page 4, ¶1.1); for each test sequence, a report is created using the new method to determine genotypic resistance. A set of "Profiles" is automatically calculated for each drug. A profile consists of a set of Hot Spots (either positive or negative). To belong to a profile, a test sequence must obey to all of the positive Hot Spots, and may not belong to any of the negative Hot Spots. The mean and median phenotypic resistance are also calculated for each Profile (see Exhibit B at page 4, ¶1.1).

The inventors further declare that the Hertogs report discloses in Exhibit B at page 8 examples of drugs used in the method as claimed. The inventors further declare that the Hertogs report discloses in Exhibit B at page 8 the following note: "he[sic] phenotypes and sequence data should be imported, the hot spots should be correct and the phenotype set should be calculated before starting the test script."

The inventors further declare that the Hertogs report discloses in Exhibit B at page 21 various fields in an Excel file which include: sequence identifier; drug (compound tested), fold resistance observed in the antivirogram linked to a sequence; phenotypic call for the real data; and original virtual fold resistance.

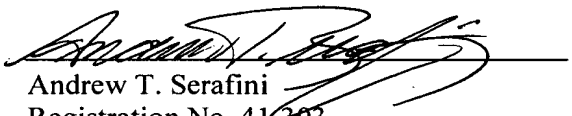
The Hertogs report discloses in Exhibit B at page 24 under the header "7. Test Summary Log" the following: "Verify the scoring of genotypic calls in the VircoGen™ database (virtual phenotypes)".

The inventors declare on page 2 of the §1.131 Declaration that the Hertogs report in Exhibit B, therefore, shows in detail all the steps to be performed to arrive at the result as claimed in Exhibit A.

Since the Hertogs *et al.* reference has been antedated, applicants respectfully request that the rejection of claims 1-4, 8, 13, 16-25, 28-32 and 39-41 under 35 U.S.C. § 102(a) be withdrawn.

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants submit that this application is now in condition for allowance.

Date: July 14, 2006



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